


Investments for Patient Safety and Our Future Growth

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Holistic Remediation and Transformation Program *Elevate*

As a global MedTech company, we want to be recognized for the quality, value, and innovation that our products, services, and people bring to society every day. We consistently demonstrate our unwavering commitment to patient safety and maintain a quality-first mindset in all that we do. Within Olympus, we have identified areas to improve our quality management by establishing stronger processes and compliance, and optimizing how we operate across our regions to meet stakeholder and regulator expectations.

That is why we have launched *Elevate*, a multi-year program that started in fiscal year 2024, focused on our quality transformation journey. The program is led by a strong global cross-functional team and encompasses 20 workstreams driving initiatives to meet our regulatory commitments, build for our future, and strengthen our cultural foundation. This is a companywide transformation that has four core goals.

 For the detailed work streams of the *Elevate* program, please refer p. 37.

Our key long-term goals are:

- 1 | Strengthening our patient safety focus and product quality culture
- 2 | Embedding sustainable, repeatable processes and compliance
- 3 | Fostering constructive relationships with health authorities
- 4 | Leveraging quality as a competitive advantage

Elevate will be an important enabler for innovation, growth, and improved profitability through sustainable benefits such as improved lifecycle management and digitally enabled processes to reduce costs, improve effectiveness, and shorten the time to develop, clear, and launch products.

Topics: Infection Prevention

Comment from a Chief Medical Officer

Strengthening Infection Prevention

In our pursuit of excellence in infection prevention, I am convinced that we are on the right path, but there remain opportunities for further improvement. This is a pivotal moment for us to advance patient safety by looking at ourselves critically and striving to deliver optimally designed products and procedures.

Our Infection Prevention team of scientists and physicians are committed to comprehensive stewardship by advocating best infection prevention practices at every stage of a product lifecycle. Providing expert knowledge to ensure effective cleaning and reprocessing in a range of real-world settings is crucial for continuous improvement that elevates the standard of care, with a patient-centric focus.



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Improving Our QARA Capabilities and Keeping Our Focus Always on the Patient

Boris Shkolnik
Executive Officer and
Chief Quality Officer (CQO)



Being the Clinical Voice to Ensure Patient Focus

John de Csepel, MD
Executive Officer and
Chief Medical Officer (CMO)



Committing to Our Core Values, Key Components in Our Decision-making

When I joined Olympus in 2022, each facility was run regionally, and while effective in those areas, they lacked harmony with our global processes. Over these past two years, we have made significant progress in establishing a global quality assurance and regulatory affairs (QARA) organization that has deep reach into our operating facilities and strong connections into the business and functional organizations across Olympus. While we still have a lot of work to do, we are improving our focus on patient safety, quality, and compliance, and we are now much more agile when responding to challenges.

In fiscal year 2024, we updated Our Core Values with emphasis on patient safety and ensured that patient safety was at the core of all decisions that we make as a company. By working with regulatory authorities around the world, we are able to improve our products and processes.

Not only are our processes and products transforming, but also our culture, which is evolving to emphasize continual improvement, centered on the patient. By consolidating our processes globally, decision-making, such as for product recalls, is now faster and more visible, which helps our employees build confidence and creates more independence within the organization to make decisions with patients in mind as the highest priority.

Empowering Employees and Improving Systems through *Elevate*

Elevate, which has encompassed our remediation activities, is one such system that has united teams across R&D, operations, supply chain, service, repair, and regional organizations, engaging them in our improvement actions and empowering them to drive these actions forward. In its second year, *Elevate* is designed to engage all parts of the global Olympus organization and focuses on ensuring patient safety, improving the quality of our products and services, and improving our compliance with global regulations. One of the most notable aspects of the *Elevate* program is the work the teams are doing in improving our patient focused culture and helping our overall organization mature our

approach as a MedTech company.

Through *Elevate*, our teams have completed required design validation activities and are currently completing process validations across our manufacturing facilities. We have also implemented several global quality system processes focused on improving effectiveness and are standardizing our approach across our operating facilities.

We have also made investments into our QARA organization to complement existing talent and have established a global reporting structure as well as hired MedTech leaders. The investments made to enhance our safety, quality, and compliance are supporting the completion of our remediation activities, strengthening our QARA organization, and enabling improvements in our safety, quality, and compliance culture.

Working with Regulators to Reinforce Our Focus on the Patient

As we work with regulators, we are being very transparent. Our focus has been on ensuring we meet all agreed upon commitments, proactively sharing progress updates, and transparently communicating both challenges and timeline adjustments for all activities. While remediation continues, we continue to learn, and our efforts are already having an effect.

As we mature our QARA organization, I anticipate even stronger engagement and partnership across our teams. Our goals are to continue enhancing the safety of our products and solutions, and I also expect shorter approval cycle times for new products. We are continuing to enhance our quality engineering teams focused on human factors engineering, reliability, risk management, software quality engineering, and cybersecurity to further contribute to the safety and effectiveness of our future solutions.

From Clinical Practice to Business Strategy and Back Again—The Role of CMO

The CMO role is multifaceted. First and foremost, I am the leader of the Medical & Scientific Affairs (MSA) organization, which has five very different subfunctions: Clinical Research, Medical Affairs, Health Economics, Medical Safety, and Professional Education. Although each are quite different, together they can effectively address barriers to care such as regulatory approvals, reimbursement, and physician training. When Olympus overcomes these barriers, patients get access to high quality care with Olympus' leading products.

The CMO also has the responsibility for contributing to business strategy, discovering new growth opportunities, and being the clinical voice on the Group Executive Committee (GEC). It is my job to always advocate from the patient's perspective, thinking about each issue in terms of safety and expected outcomes. To best represent clinical and patient perspectives, I draw on my own experience as a practicing surgeon as well as regular visits with Olympus customers, where I gain valuable patient care insights.

Decision-making with Patient Safety as Our Top Priority

Patient safety is our company's top priority, and that means if we find an issue, we seek to understand the root cause and consider all options with our patients' well-being as our top priority. MSA has a dedicated Medical Safety team made up of doctors and nurses around the world. They are very experienced at taking a risk-based approach to decisions. By looking at data related to causation and the current state of care, they can make judgments, in partnership with their quality and regulatory colleagues as well as other stakeholders, about needed changes in product design, instructions for use, and manufacturing processes.

Elevate was established to enable Olympus to be a first-class patient safety and quality-focused MedTech company. One of its key components is complaint handling. How we gather feedback from clinicians in a timely manner and evaluate those insights is critical. If we have a patient safety issue, we may need to take action quickly. Our Medical Safety team of professionals are on standby around

the clock to talk to clinicians who have raised concerns. This team knows the questions to ask to get the answers Olympus needs to make informed judgments.

Enhancing Access to Cancer Detection

Our role in raising awareness of colorectal cancer screening is critical. We support large-scale public awareness campaigns in many countries where screening rates are below guidelines. Early detection saves lives. In the United States, over 90% of colorectal cancer-related deaths could be prevented with early detection^{*1}, however only two thirds of the population of those aged 50 to 75 is up to date with screening^{*2}.

Providing colonoscopic procedural training is essential to achieve this objective. As the worldwide leader in endoscopy, we have a responsibility to address the current global shortage of trained endoscopists to ensure patients receive a timely diagnosis in their own communities.

Goals and Outlook for the Future

I hope to continue to contribute to the culture at Olympus such that patient focus remains top of mind for every one of our employees. Moving forward, my goal is to seek new ways to embed patient safety into every aspect of the product lifecycle. For example, MSA professionals now participate in the new product development process, which allows us to focus on patient safety at the very beginning of the R&D process. Then at product launch, we provide procedural training so that Olympus products can be used as intended. As our products become adopted into everyday practice, we want to be sure our product surveillance is of the highest quality so we can identify and act upon any issues early on. If we can do this, Olympus and our patients around the world will benefit from safe products that provide desired outcomes.

^{*1} SEER Cancer Stat Facts: Colorectal Cancer." Surveillance, Epidemiology, and End Results (SEER) Program, National Cancer Institute, 2023

^{*2} "Use of Colorectal Cancer Screening Tests—Behavioral Risk Factor Surveillance System, United States, 2020." Morbidity and Mortality Weekly Report (MMWR), July 9, 2021